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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,970	12/03/2001	Eva Redei	048626-5003-01 (NU 99011)	8481

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,970	REDEI, EVA	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 17-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. On page 20 of the specification, depression is defined to equate with depressive disorders and further to exclude anxiety. For the purpose of examination these definitions have been accepted as they apply to the claimed invention.

Information Disclosure Statement

2. The information disclosure statement filed 03 December 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The references were not scanned into the application file at the time of examination, perhaps through Office error. The patent references listed have been considered. The non-patent references have not been considered because copies of the cited references could not be readily obtained. If the non patent references are provided in response to this Office action they will be listed as considered on the Form PTO-1449 without the necessity of the applicants filing of an additional information disclosure statement.

Claim Objections

3. Claim 3 is objected to because of the following informalities: In line 2 there is a left parentheses before the term "Corticotropin" that should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to method of using peptidometics with corticotropin release inhibiting factor activity (CRIF) to treat depressive disorders. The specification distinguishes between peptides and peptidometics as different compositions on page 2, lines 18-19. The specification defines polypeptides on page 20 as including polymers of amino acid analogs linked by peptide bonds. The specification discusses use of CRIF and CRIF-like peptides as guides for generation of peptidometics on page 10, lines 18-21. Therefore the specification describes peptidometics as different from and not comprising peptides, while claims 17-24 are drawn to peptidometics comprising peptides. The specification does not describe the structure of peptidometics with CRIF activity. The specification does not describe methods of using peptidometics with CRIF activity to treat depressive disorders because the structures of peptidometics required by the claimed methods are not described.

6. Claims 3 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a

determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must treat depressive disorders with peptidometics with CRIF activity. For the reasons discussed below there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The specification distinguishes between peptides and peptidometics as different compositions on page 2, lines 18-19. The specification defines polypeptides on page 20 as including polymers of amino acid analogs linked by peptide bonds. The specification discusses use of CRIF and CRIF-like peptides as guides for generation of peptidometics on page 10, lines 18-21. Therefore the specification describes peptidometics as different from and not comprising peptides. The specification does not provide guidance as to what are effective structures of peptidometics with CRIF activity. Claims 17-24 are drawn to methods of using peptidometics that comprise peptide sequences, which is contrary to the definition of peptidometics discussed above.

c) The specification does not provide working examples of the claimed methods.

d) The nature of the invention, treatment of depressive disorders, is complex.

e) U.S. Patent No. 5,334,702 (cited in the Form PTO-1449 filed 03 December 2001 shows peptidometics that mimic antibody binding sites. WO 93/17073 describes methods of

synthesizing peptidometics without peptide bonds, but does not show peptidometics that have CRIF activity.

f) The skill of those in the art of pharmacology is high.

g) The predictability of the art of peptidometics with CRIF activity cannot be assessed.

h) The claims are broad in that they require use of undescribed compounds.

The skilled practitioner would first turn to the instant specification for guidance in practicing the claimed invention. However, the specification does not provide detailed guidance or working examples to make or use peptidometics with CRIF activity, and to make peptidometics comprising peptides. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art doe not show peptidometics with CRIF activity.. Finally, said practitioner would turn to trial and error experimentation to practice the claimed method. Such represents undue experimentation.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00. On approximately 12 January 2004 Art Unit 1631 will move to the new USPTO Alexandria, VA facility. At that time the phone number of the examiner will change to (571) 272-0714. Phone calls to the previous phone number will be referred to the new phone number for 60 days after the move date.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

John S. Brusca
Primary Examiner
Art Unit 1631

jsb